

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF SOUTH CAROLINA**

The United States of America, the	)	
States of North Carolina, California,	)	
Colorado, Delaware, Florida, Georgia,	)	
Illinois, Indiana, Iowa, Louisiana,	)	
Michigan, Minnesota, New Jersey, New	)	
York, Tennessee, Texas, Virginia and	)	
Wisconsin, <i>ex rel.</i> Scarlett Lutz, Kayla	)	
Webster, Dr. Michael Mayes and Chris	)	
Reidel,	)	
Plaintiffs,	)	CIVIL No. 14-cv-00230-RMG
vs.	)	(Consolidated with 9:11-cv-1593-RMG
	)	and 9:15-cv-2485-RMG)
Berkeley Heartlab, Inc., BlueWave	)	
Healthcare Consultants, Inc., Latonya	)	
Mallory, Floyd Calhoun Dent, III and	)	
Robert Bradford Johnson,	)	
Defendants.	)	

**DEFENDANT LATONYA MALLORY’S MEMORANDUM IN SUPPORT OF  
SUMMARY JUDGMENT OF THE INTERVENOR’S COMPLAINT**

**SUMMARY AND NATURE OF THE CASE**

The government has filed a complaint in intervention (ECF No. 75) alleging False Claims Act (“FCA”) violations, payment of mistake of fact, and unjust enrichment claims against defendant LaTonya Mallory (“Mallory”) and others. The alleged FCA violations arise from alleged Anti-Kickback Statute (“AKS”) violations for (1) laboratories’ payment of process and handling fees; (2) the laboratories’ agreements with independent contractors; and (3) alleged waivers of patient co-pays and deductibles with respect to laboratory tests paid by Tricare. (*See* ECF No. 75 ¶¶ 96-108, 150-156).

**STATEMENT OF THE FACTS**

On November 8, 2008, Mallory founded Health Diagnostics Laboratory, Inc. (“HDL”) and is its former CEO. (*See* ECF No. 75 ¶¶ 92-93). HDL was one of several specialty blood

testing laboratories that developed a panel of advanced lipid tests. HDL was a large company and at one point had approximately 1,000 employees.

HDL reimbursed physicians, physician practices, and laboratories for blood specimens drawn and processed for shipment. (*See* ECF No. 75 ¶ 156). HDL and the physicians, practices, and laboratories entered into “Process and Handling Agreements” (“P&H agreements”) wherein the physician, practices, and laboratories agreed that they would not bill, receive, or collect any reimbursement for P&H fees or collection fees from any third party payor, including commercial insurers and governmental programs such as Medicare. Not all of the physicians, practices, and laboratories had a P&H agreement with HDL. Not all of physicians, practices, and laboratories who had a P&H agreement with HDL were reimbursed for P&H.

Prior to the OIG’s June 25, 2014 Special Fraud Alert, P&H agreements and the payment of P&H fees were common in the industry.<sup>1</sup> *See, e.g.* Mallory’s depo.<sup>2</sup>; Ex. 1 (Excerpt Udell depo. stating that “labs historically prior to the OIG getting involved in laboratory services, we are talking about Labcore [sic], Quest, all these major firms, were charging handling fees or paying handling fees to doctors. ... That’s just the way the industry was. ... [P&H payments] would typically range from \$15.00 to \$19.00 to \$20.00”); Ex. 2 (Quest email and Specimen Collection Agreement to HDL); Ex. 3 (HDL-Quest P&H Agreement); Ex. 4 (Singulex P&H Agreement); Ex. 5 (Atherotech P&H Agreement); Ex. 6 (Code Map Opinion). HDL had at least 313 P&H agreements with other labs. Ex. 7 (Lab P&H Agreements). It had at least 3,392 P&H

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<sup>1</sup> HDL did not pay P&H fees after the Special Fraud Alert.

<sup>2</sup> Mallory’s deposition transcript is not yet final. The undersigned will file it with the Court when it is received in final form.

agreements (physician, practices, and lab) and an attorney reviewed each one. Ex. 8 (Attorney review P&H, excerpted pages 1-3).<sup>3</sup>

Mallory continuously sought input from and consulted with counsel throughout her time at HDL and before it was formed. *See* Ex. 9 (Ropes & Gray PowerPoint presentation to the government, p. 14). The P&H Agreement was drafted by the attorneys at LeClairRyan. In 2009, Mallory provided a “bare bones” draft P&H agreement to Attorney Dennis Ryan (at LeClairRyan). She asked Attorney Ryan to review it and make any changes “to make sure that it is not misconstrued as inducement.” Ex. 10 (Draft P&H to LeClairRyan). Attorney Ryan “bounced [Mallory’s] inducement question” off Attorney Patrick Hurd, also at LeClairRyan. Ex. 11 (LeClairRyan October 2009 emails). Attorney Ryan recollected that P&H fees did not run afoul of AKS and confirmed that was still the case. *See* Ex. 11.

Another LeClairRyan attorney Mike Ruggio examined the P&H agreement and analyzed HDL’s payment of P&H fees. He also facilitated an independent time and motion study by Exponent to assign a value for the process and handling fee arrangements. Ex. 12 (Ruggio opinion letter). After analyzing the Exponent study, Attorney Ruggio opined that a P&H fee up to but not exceeding \$36.03 would “fall into the safe harbor exceptions under Anti-Kickback statutes (and Civil False Claims Act) ...” Ex. 12.

The entire structure of the HDL/BlueWave relationship and agreement was developed by Attorney Ryan. Attorney Ryan structured the relationship in an attempt to keep HDL out of a potential Berkeley lawsuit. (Mallory Depo). Attorney Ryan also drafted the BlueWave Sales Agreement. *See* Ex. 13 (LeClairRyan edits to Sales Agreement); Ex. 14 (LeClairRyan email to

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<sup>3</sup> The list of 3,392 P&H agreements is not a list of HDL active accounts (because many of these accounts became inactive) nor is it a list of total HDL accounts (because many HDL accounts did not enter into P&H agreements and/or did not receive P&H payments). The entire list is 794 pages and Mallory attaches as Exhibit 8 the first 3 pages.

Attorney Gene Sellers asking him to review and confirm the terms for the Sales Agreement with LeClairRyan edits to the terms).

In 2012, HDL hired Patton Boggs, LLP to analyze whether federal law prohibits the routine waiver of patient responsibility payments for laboratory tests ordered by physicians from HDL. Ex. 15, p. 1 (Patton Boggs opinion). Patton Boggs concluded that legal and policy considerations demonstrate that the routine waiver of patient responsibility payments is not a violation of federal law. Ex. 15, pp. 10-11. It also analyzed state law and noted that there were a limited number of states that expressly prohibited routine waivers of patient liability amounts. Ex. 15, p. 11; Ex. 16 (Patton Boggs state law review). HDL began collecting patient liability amounts in those states.

In the summer 2012, HDL hired Attorney Derek Kung as in-house counsel. Attorney Kung analyzed HDL's relationship with BlueWave, its payment of P&H fees, and the waiver of co-pays, co-insurance and deductibles. He concluded that "there is not any bad intent" with respect to any of these arrangements. Ex. 17, p. 1 (Kung memo). Attorney Kung thought that HDL should "try to move away from P&H" because the OIG would identify the practice as suspect. Ex. 18 (Excerpt Kung depo.).

HDL implemented a compliance program and hired another attorney, Kathy Johnson, as its Chief Compliance Officer. Attorney Johnson evaluated HDL's practices for compliance and also went on "ride-alongs" in the field with the sales force. HDL also began "Project Twilight" to establish draw sites and move completely away from the payment of P&H. HDL eventually opened 10 – 12 draw sites and spent millions to get these sites up and running. (Mallory depo.).

In fall 2012, HDL hired the law firm Ropes & Gray. In January 2013, the government issued a subpoena to HDL requesting 37 categories of documents including agreements between

HDL and BlueWave, P&H agreements, waiver of co-pays or deductibles, and HDL tests. Ex. 19 (Subpoena to HDL). In April 2013 HDL sent its first production of documents to the government, including all contracts, account forms with physicians, and employee lists. Ex. 20 (HDL April 2013 production); Ex. 21 (HDL April 2013 production part 2).

While producing voluminous documents to the government, the Ropes & Gray attorneys were also analyzing HDL's payment of P&H fees. In spring 2013, Laura Hoey from Ropes & Gray said that the government would view the payment of P&H fees as suspect. (Mallory depo.). Mallory asked Laura Hoey if she thought HDL violated the AKS or Stark Law, and she told Mallory "no." (Mallory depo.).

By this point HDL had well over a dozen attorneys: Dennis Ryan (who worked for LeClairRyan and joined HDL in February 2012), Charles Simms (LeClairRyan), Patrick Hurd (LeClairRyan), Mike Ruggio (LeClairRyan), Matthew Haynes (LeClairRyan), Derek Kung (HDL), Doug Sbertoli (HDL), Nick Pace (HDL), Kathy Johnson (HDL), Lawrence Freedman (Patton Boggs), Laura Hoey (Ropes & Gray), Brien O'Connor (Ropes & Gray), David Rhinesmith (Ropes & Gray), Stacey Tromble (Ropes & Gray), and Michael Lambpert (Ropes & Gray).<sup>4</sup> Mallory "begged" the attorneys to all get together, work towards a consensus, and advise HDL on how to proceed. (Mallory Depo.). The attorneys began to do that.

On May 7, 2013, the government and HDL reached a confidentiality agreement and HDL moved onto the next portion of production. Ex. 23. On May 10, 2013, it produced additional documents. Ex. 24. On May 24, 2013, HDL produced another batch of documents. Ex. 25. In

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<sup>4</sup> This list does not account for all HDL's attorneys. For example, the March 2014 Ropes & Gray invoices reflect that attorneys Deborah Gersh, Lisa Guo, Christine Moundas, Jennifer Romig, Joseph D'Imperio, Martha Harrison, Peter Holman, Jessica Jones, Nordo Nissi, and others performed work for HDL in addition to those named above. Ex. 22 (Ropes & Gray February 2014 invoices).

May 2013, the government said it was interested in learning more about the P&H agreement and HDL agreed to provide the government with a witness. Ex. 26.

In June 2013, HDL indicated that it was producing documents from 20 different custodians, including Mallory. Ex. 27. In July 2013, HDL sent an additional 13,830 documents to the government, including documents collected from Mallory and related to (1) remuneration to health care providers; (2) copayment, coinsurance, or deductible waivers; (3) balance billing practices; (4) coding, billing, reimbursement, or the customization or modification of requisition forms; (5) practices or provision of phlebotomists, including related leases; and (6) compliance with federal laws. Ex. 28. By September 2013, HDL was on Production Volume 12 and had produced over 272,000 documents. Ex. 29; Ex. 30. In October 2013, HDL produced an updated report regarding its payments to BlueWave. Ex. 31. By November 4, 2013, HDL had produced the vast majority of its responsive documents to the government. Ex. 32.

After approximately 6 months of research, analysis, and discussion, in fall 2003 the attorneys reached a consensus. Ropes & Gray revised the P&H agreement, sent it to Attorney Kung, who forwarded to Mallory, Attorney Johnson and others, saying that it did not contain “anything controversial.” Ex. 33 (Ropes & Gray email fall 2013).

On December 14, 2013, the government served a Civil Investigation Demand on HDL. HDL provided its initial responses on January 10, 2014. Ex. 34 (January 2014 CID Email). It provided its First Supplemental Responses on January 29, 2014. Ex. 35 (January 29, 2014 CID Email). It provided its Second Supplemental Responses on February 10, 2014. Ex. 36 (February 2014 CID Email). Within these responses, HDL reiterated the facts and circumstances which are now underlying this case and it directed the government to the documents it previously produced. *See, e.g.*, Ex. 37, Response Nos. 2c, 3a-3h (regarding P&H); Ex. 38, Response Nos.

3d, 3g, 3h (regarding P&H); Ex. 38, Response No. 4 (regarding copay and deductible waivers); Ex. 39, Response No. 4 (regarding copay and deductible waivers); Ex. 37, Response Nos. 8b, 8d, 8e (regarding the HDL/BlueWave agreement and payments to BlueWave); Ex. 37, Response Nos. 1a-1l, 9b (regarding HDL's tests); Ex. 38, Response Nos. 1d, 1l, 1m, 1o, 1p (regarding HDL's tests); Ex. 39, Response Nos. 1, 1l, 1o (regarding HDL's tests). Even though the government had actual knowledge of the facts underlying the purported violations, it continued to pay HDL claims.

In January 2014, HDL asked the government whether the payment of P&H fees constituted a kickback. The government refused to take a position on the issue. Ex. 40 (January 2014 emails). In April 2014, Ropes & Gray reached out to the government regarding the criminal investigation. Ex. 41. The government informed Ropes & Gray that it had closed the criminal case. Ex. 41.

During this entire time, the government continued to pay the claims. In fact, the government paid HDL's claims through at least August 7, 2015, the date its Intervenor Complaint was filed. Ex. 42, ¶¶ 56, 59, 60, 61, Appendix 5, Appendix 6, Appendix 7 (Excerpt from Hines' Report). This was nearly 1 year after Mallory left HDL, nearly 6 months after the government entered into the settlement agreement with HDL, and 1 month after HDL filed bankruptcy. Ex. 43 (HDL Settlement Agreement).

### **SUMMARY JUDGMENT STANDARD**

Summary judgment is appropriate if a party shows "that there is no genuine dispute as to any material fact" and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Summary judgment should be granted "only when it is clear that there is no dispute concerning either the facts of the controversy or the inferences to be drawn from those facts."

Pulliam Inv. Co. v. Cameo Props., 810 F.2d 1282, 1286 (4<sup>th</sup> Cir. 1987). “In determining whether a genuine issue has been raised, the court must construe all inferences and ambiguities in favor of the nonmoving party.” HealthSouth Rehab. Hosp. v. Am. Nat’l Red Cross, 101 F.3d 1005, 1008 (4<sup>th</sup> Cir. 1996). “A mere scintilla of proof, however, will not suffice to prevent summary judgment.” United States ex rel. Herrera v. Danka Office Imaging Co., 91 Fed. Appx. 862, 863 (citations omitted). “A complete failure of proof concerning an essential element of the nonmoving party’s case necessarily renders all other facts immaterial.” Id. at 864 (citation omitted).

### **THE FALSE CLAIMS ACT**

In order to establish a violation of the False Claims Act, a plaintiff must show that: (1) there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material to the government’s decision to pay a claim; and (4) that caused the government to pay out money or to forfeit moneys due. *See* United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 376 (4<sup>th</sup> Cir. 2008); Universal Health Services, Inc. v. United States ex rel. Escobar, -- U.S. --, 136 S.Ct. 1989, 1996, 195 L.Ed.2d 348 (2016).

### **ARGUMENT**

#### **I. MALLORY’S PURPORTED VIOLATIONS WERE NOT MATERIAL TO THE GOVERNMENT’S DECISION TO PAY A CLAIM**

“The FCA attaches liability, not to the underlying fraudulent activity, but to the claim for payment.” United States ex re. Donegan v. Anesthesia Associates of Kansas City, PC, 833 F.3d 874, 876 (8<sup>th</sup> Cir. 2016) (citation omitted). “A misrepresentation about compliance with a statutory, regulatory, or contractual requirement *must be material* to the Government’s payment decision in order to be actionable under the False Claims Act.” Universal Health Services, Inc.



v. United States ex rel. Escobar, -- U.S. --, 136 S.Ct. 1989, 1996, 195 L.Ed.2d 348 (2016) (italics added). The Supreme Court emphasized that the materiality requirement is “rigorous” and “demanding” and can be adjudicated on a motion for summary judgment. Id., 136 S.Ct. at 2003, 2004, n. 6.

“The False Claims Act is not ‘an all-purpose antifraud statute’ or a vehicle for punishing garden-variety breaches of contract or regulatory violations.” Id. 136 S.Ct. at 2003 (quoting Allison Engine Co., Inc. v. U.S. ex rel. Sanders, 553 U.S. 662, 672, 128 S.Ct. 2123, 2130, 170 L.Ed.2d 1030 (2008)). “A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment.” Id. “Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant’s noncompliance.” Id.

Rather, materiality “look[s] to the effect on the likely or *actual* behavior of the recipient of the alleged misrepresentation.” Id., 136 S.Ct. at 2002 (quoting 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4<sup>th</sup> ed. 2003)) (emphasis added). “[P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.” Id., 136 S.Ct. at 2003. “Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.” Id.

“[C]ourts need not opine in the abstract when the record offers insight into the Government’s actual payment decisions.” United States ex rel. McBride v. Halliburton Co., 848

F.3d 1027, 1032 (D.C. Cir. 2017) (citing Universal Health Services, 136 S.Ct. at 2002). The Court here has the benefit of hindsight and should not ignore what actually occurred. *See Id.* at 1034.

Looking at the “actual behavior” of the government, *see Universal Health Services, Inc.*, 136 S.Ct. at 2002, it continued to pay claims knowing of Mallory’s purported misrepresentations. In fact, the government “*consistently reimburse[d]* these claims with full knowledge of the purported noncompliance.” United States ex rel. Petratos v. Genentech, Inc., 855 F.3d 481, 490 (3<sup>rd</sup> Cir. 2017). It paid claims through at least August 7, 2015, the date its Intervenor Complaint was filed. Ex. 42, ¶¶ 56, 59, 60, 61, Appendix 5, Appendix 6, Appendix 7 (Excerpt from Hines’ Report). It paid claims well after Mallory left HDL, after it settled with HDL, and after HDL filed bankruptcy. Ex. 43 (Government/HDL settlement agreement). Mallory’s purported misrepresentations were not “material to the [g]overnment’s payment decision” and thus are not actionable under the False Claims Act. Universal Health Services, Inc., 136 S.Ct. at 1996. The Court should therefore grant Mallory’s motion for summary judgment.

## **II. THERE IS NO EVIDENCE THAT THE PURPORTED MISREPRESENTATIONS CAUSED THE GOVERNMENT TO DISBURSE MONEY OR FORFEIT MONEY DUE**

The government alleges that because the defendants violated the Anti-Kickback Statute in their quid pro quo arrangements, any and all claims submitted to the government for laboratory testing, regardless of how the patients came to be customers of the defendants, violated the FCA. Ex. 42, ¶ 66 (Hines’ report stating “I understand that whether a patient was prescribed a test by a specific physician or any physician in a larger group or practice, the claim was tainted by a P&H payment to any physician in the practice for the purpose of identifying an improper claim”).

The plaintiff's position paints too broad of stroke. United States v. Medco Health Systems, Inc., 2016 WL 7408843, \*5 (D.N.J. 2016) (on appeal, Greenfield v. Medco Health Solutions, 3rd Cir., January 23, 2017). The plaintiff must show the link between the defendants' alleged quid pro quo arrangements and each of the purported false claims submitted to the government. As explained by the Court in Medco Health Systems, this view is consistent with the FCA:

The evidence in the record shows that from 2008 to 2012, defendants billed the federal government for twenty-four hemophilia patients, resulting in 897 invoices submitted to the government for payment in the amount of \$39,137,649.00. This data does not, however, show that any of these twenty-four patients were referred from HANJ/HSI or an HTC as a result of defendants' donations.

Plaintiff argues that because defendants violated the AKS in their quid pro quo arrangement with HANJ/HSI, any and all claims submitted to the government for hemophilia patients, regardless of how the patients came to be customers of defendants, violate the FCA because defendants certified their compliance with the AKS for each of those claims. Plaintiff's argument is too broad a stroke. Instead, plaintiff must show each claim submitted to the government for payment would not have been paid by the government had it known about defendants' false representation that they complied with the AKS. The remedies provision of the FCA supports this view.

Thus, the FCA contemplates that a person violates the FCA each time he knowingly presents a false claim for payment to the government, and that person is liable for ... each false claim. The FCA does not suggest that one false claim for payment submitted to the government causes all other claims for payment, regardless of whether those other payments were shown to be false, to be violations of the FCA. ...

Here, plaintiff has shown that defendants submitted claims to the government for hemophilia products, defendants certified their compliance with the AKS for those claims, and based on defendants' certification of compliance, the government paid defendants. While accepting for the purposes of resolving the parties' motions the premise that defendants' relationship with HANJ/HSI violated the AKS, these proofs would be sufficient to establish plaintiff's FCA claim, but only if he had also shown that each of defendants' claims to the government for payment was directly linked to defendants' donations to HANJ/HSI. Because plaintiff has not shown the link between defendants' 24 federally insured customers and defendants' donations to HANJ/HSI, plaintiff's FCA claim fails.

Id. at \*5-7.

The view of the Court in Medco Health Systems is consistent with the opinion in this District prohibiting statistical sampling. In United States ex rel. Michaels v. Agape Senior Community, Inc., 2015 WL 3903675 (D.S.C. 2015), the plaintiff alleged that the defendant “orchestrated a widespread fraudulent scheme of submitting false claims to the federal healthcare programs of Medicare, Medicaid, and Tricare, seeking reimbursement for nursing home-related services.” Id. at \*1. The Court held that the plaintiff could not use statistical sampling to prove liability or damages. This issue was certified for review, however, the Fourth Circuit dismissed it as improvidently granted. United States ex rel. Michaels v. Agape Senior Community, Inc., 848 F.3d 330, 341 (4<sup>th</sup> Cir. February 14, 2017).

In reaching its conclusion, the District Court agreed with the reasoning in United States v. Friedman, No. 86-0610-MA (D. Mass. July 23, 1993), wherein the Court “declined to allow statistical sampling based on the existence at trial of discrete claims that may be analyzed, discussed, and subject to cross-examination.” Michaels, 2015 WL 3903675, \*7; *see also* Medco Health Systems, 2016 WL 7408843, \*7 (the plaintiff must show “that each of defendants’ claims to the government for payment was directly linked to defendants’ donations to HANJ/HSI. Because plaintiff has not shown the link between defendants’ 24 federally insured customers and defendants’ donations to HANJ/HSI, plaintiff’s FCA claim fails”).

The importance of analyzing, discussing, and subjecting the claims to cross examination is crucial here because not all of the physicians or physician practices that had a P&H agreement actually received P&H fees. Moreover, the plaintiff’s expert Eric Hines incorrectly assumes that if one physician in a practice received P&H fees, all the claims from that practice were tainted. Ex. 42, ¶ 66. For example, Relator Mayes testified that the other physicians in his practice

received P&H fees from HDL. Ex. 44 (Excerpt Mayes Depo.). Under the government’s theory of liability, even if Relator Mayes did not receive P&H fees from HDL, Mallory’s “P&H scheme” would have caused the government to disburse money for HDL tests ordered by Relator Mayes. Even assuming that “there was a false statement or fraudulent course of conduct” and that the “government [] pa[id] out money,” *see Wilson*, 525 F.3d at 376, there is no evidence that the former “caused” the latter for each claim that the government paid. *See Agape Senior Community, Inc.*, 2015 WL 3903675, \*7; *Medco Health Systems, Inc.*, 2016 WL 7408843, \* 5-7. The government’s theory of liability paints too broad of stroke. *Medco Health Systems, Inc.*, 2016 WL 7408843, \*5. The Court should therefore grant Mallory’s motion for summary judgment.

### **III. THE PURPORTED STATEMENTS OR CONDUCT WERE NOT OBJECTIVE FALSEHOODS**

To satisfy the first element of a FCA claim, i.e. that there was a false statement or fraudulent course of conduct, “the statement or conduct alleged must represent an objective falsehood.” *Wilson*, 525 F.3d at 376 (citations omitted). As a result, “imprecise statements or differences in interpretation growing out of a disputed legal question are [] not false under the FCA.” *Id.* at 377 (citations omitted). To prove a violation of the AKS, the plaintiff must demonstrate the following elements: “(1) remuneration offered or paid; (2) in order to induce the referral of government healthcare business; (3) done knowingly and willfully.” *Klaczak v. Consolidated Medical Transport*, 458 F. Supp. 2d 622, 686 (N.D. Ill. 2006) (citing 42 U.S.C. § 1320a-7b(b)(2)(B)). It cannot make this showing here.

The AKS “criminalizes the payment of any funds or benefits designed to encourage an individual to refer another party to a Medicare provider for services to be paid for by the Medicare program.” *United States ex rel. Ruscher v. Omnicare, Inc.*, 663 Fed. Appx. 368, 374

(5<sup>th</sup> Cir. 2016) (citation omitted). The focus is on the “purpose” of the payment, not the consequence. *See Id.* “There is no AKS violation [] where the defendant merely hopes or expects referrals from benefits that were designed wholly for other purposes.” *Id.*; *see also United States ex rel. McDonough v. Symphony Diagnostic Services, Inc.*, 36 F. Supp. 3d 773, 777 (S.D. Ohio 2014) (“[t]he law does not criminalize *referrals*; rather, it criminalizes knowing and willful acceptance of remuneration in return for such referrals”) (citation omitted); *Klaczak v. Consolidated Medical Transport*, 458 F. Supp. 2d 622, 686 (N.D. Ill. 2006) (“The various Medicare ‘safe harbors’ define a subset of clearly legal conduct, but that does not mean that anything outside the ‘safe harbors’ violates the AKS”).

For example in *Ruscher*, the Relator alleged that the defendant offered skilled nursing facilities, prompt payment discounts, and debt forgiveness in exchange for contract referrals. 663 Fed. Appx. at 373. By doing so, the defendant allegedly violated the FCA by making and causing the skilled nursing facilities to make false claims to Medicare and Medicaid by falsely certifying compliance with the AKS when submitting claims for reimbursement. *Id.* The Court examined the Relator’s evidence and held that the defendant’s settlement negotiation and debt collection practices were not designed to induce Medicare and Medicaid referrals from skilled nursing facilities. *Id.* at 374. Therefore there was no AKS violation. Similarly here, there is no evidence that Mallory designed the P&H fee, BlueWave structure, or co-pay/deductible waiver practices to induce referrals. Nor is there any evidence that she did so “knowingly and willfully.”

Rather, the evidence establishes that Mallory continuously sought out the advice of attorneys and asked for their guidance to make sure things were not “misconstrued as inducement.” *See, e.g.* Ex. 10 (Draft P&H to LeClairRyan). For example, in 2010, she

requested that Attorney Ryan review HDL's position paper on P&H fees to determine if HDL's position was acceptable. Ex. 45. Attorney Hurd reviewed the position paper, made one change, and sent it back to Mallory. Ex. 46, pp. 10-13. Also in 2010, Mallory forwarded a question that was submitted over HDL's website to Attorney Ryan regarding the legality of P&H fees. Ex. 47. Attorney Hurd called the complainant and Attorney Ryan assured Mallory that "[w]e are on solid ground with the OIG advisory opinion that Pat [Hurd] is sending," telling her that they will keep her posted. Ex. 47. In 2011, upon hearing that an HDL competitor called the payment of P&H fees an "inducement," Mallory requested that Attorneys Ryan and Hurd take another look at the P&H agreement. Ex. 47. She specifically asked them to tell her "what should be changed." Ex. 47. She "begged" more than a dozen attorneys to come to a consensus and tell HDL how to proceed. Attorney Kung knew that there was "not any bad intent" with respect to the payment of P&H fees, the BlueWave relationship, or the waiver of copays and deductibles. Ex. 17, p. 1.

None of the attorneys advised Mallory that any of the conduct described in the Complaint was illegal or unlawful. While some of them said the OIG may view some of the practices as suspect, this "does not render a practice *per se* illegal or unlawful, as even [plaintiff's] expert acknowledges." McDonough, 36 F. Supp. 3d at 780 (citing deposition of Kathleen McNamara<sup>5</sup>). Moreover, "OIG advisory opinions do not establish rules of decision, and are not to receive judicial deference." McDonough, 36 F. Supp. 3d at 780 (citing Christensen v. Harris Cnty., 529 U.S. 576, 587, 120 S.Ct. 1655, 146 L.Ed.2d 621 (2000)); *see also* (Complaint, ECF No. 75 ¶¶ 38-46, 77) (alleging that the plaintiff issued a number of advisory opinions on "problematic arrangements involving the provisions of clinical laboratory services"). "OIG advisory opinions, by regulation, 'have no application to any individual or entity that does not join in the request for

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<sup>5</sup> Kathleen McNamara is also the plaintiff's expert here.

the opinion. No individual or entity other than the requestor(s) may rely on an advisory opinion.” Id. (quoting 42 C.F.R. § 1008.53).

It is clear that Mallory did not knowingly and willfully intend for the waiver of copays and deductibles, the BlueWave structure, or payments of P&H to induce the referral of government healthcare business. These were simply practices within the industry as approved by extraordinarily reputable lawyers and law firms. Mallory’s conduct did not violate the AKS, thus it was not an “objective falsehood” under the FCA. The Court should therefore grant Mallory’s motion for summary judgment.

#### **IV. MALLORY DID NOT KNOWINGLY SUBMIT FALSE CLAIMS**

The plaintiff must prove that Mallory acted “knowingly” under the FCA, meaning with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information. 31 U.S.C. § 1320a-7b(g). Federal courts consider a variety of factors to determine whether a defendant acted with reckless disregard, including “(1) the defendant’s adherence to custom or industry practice; (2) the defendant’s existing knowledge or expertise; (3) any legal advice the defendant received; (4) any professional or expert advice the defendant received; (5) the defendant’s disclosure of its conduct to the government; (6) the existence of any guidance or authority from an administrative agency or court; (7) the reasonableness of the defendant’s actions, positions, or interpretations; and (8) the defendant’s motive.” (Order, ECF No. 494 at 10) (quoting James Wiseman, *Reasonable, but Wrong: Reckless Disregard and Deliberate Ignorance in the False Claims Act After Hixon*, 117 Colum. L. Rev. 435, 450-51 (2017)). The evidence here conclusively establishes that the plaintiff cannot meet the minimum requirement of reckless disregard.



Mallory adhered to the custom industry practice. As demonstrated above, it was common practice in the industry to pay and receive P&H fees. Further, in Mallory's experience, labs paid and received P&H fees. As stated by Ropes & Gray, "[r]eimbursement of the drawing party (other lab or physician) for the time and resources required to draw, process, and handle blood is a longstanding practice in the field." Ex. 9, p. 11. It was also common practice in the industry to use an outside sales force, and Mallory knew that Singulex also used BlueWave. Similarly, Pfizer used Professional Detailer, Incorporated, Ex. 49 (Excerpt Dent Depo.), and various cases throughout the country discuss outside sales forces in the healthcare industry. *See, e.g., Smith v. Biomet, Inc.*, 2004 WL 5499511, \*1 (N.D. Ind. 2004) ("Smith was a Biomet distributor in south Texas selling various Biomet products including orthopedic hips, knees and shoulders. Smith employed three sales people who worked for him as independent contractors selling Biomet products to various orthopedic surgeons"); *PharmFlex, Inc. v. Division of Employment Sec.*, 964 S.W.2d 825, 827 (Ct. App. Mo. 1997) ("The evidence before the Commission was that PharmFlex was a Pennsylvania-based corporation which provided sales and marketing support to pharmaceutical companies by utilizing sales representatives to contact physicians with information about the pharmaceutical company's products. Jennifer Bibik, a PharmFlex sales representative, worked for PharmFlex under a contract titled "Independent Contractor Agreement").

Mallory received and relied on extensive legal advice from countless attorneys. None of the attorneys advised Mallory that any of the conduct described in the Complaint was illegal or unlawful. While some of them said that the OIG may view some of the practices as suspect, this "does not render a practice *per se* illegal or unlawful, as even [plaintiff's] expert acknowledges." *McDonough*, 36 F. Supp. 3d at 780 (citing deposition of Kathleen McNamara). "OIG advisory

opinions do not establish rules of decision, and are not to receive judicial deference.” McDonough, 36 F. Supp. 3d at 780 (citing Christensen v. Harris Cnty., 529 U.S. 576, 587, 120 S.Ct. 1655, 146 L.Ed.2d 621 (2000)).

It is telling that the attorneys continued to zealously represent HDL even when it continued to engage in the allegedly illegal conduct. “The notion that a lawyer must not participate in a client’s illegal conduct is generally known and widely accepted.” Vince Farhat & Calon Russell, *“Houston, We Have a Problem”: Clients Who Engage in Unlawful Conduct During Your Representation*, American Bar Assoc. (Winter/Spring 2015) available at [https://www.americanbar.org/content/dam/aba/publications/criminaljustice/wcc\\_newsletter\\_unlawful\\_conduct.authcheckdam.pdf](https://www.americanbar.org/content/dam/aba/publications/criminaljustice/wcc_newsletter_unlawful_conduct.authcheckdam.pdf).

“ABA Model Rule 1.2(d) precludes lawyers from counseling or assisting in a client’s criminal or fraudulent conduct.” Id.; *see also* S.C. Rules Prof. Cond. 1.16(a) (“a lawyer shall not represent a client or, where representation has commenced, shall withdraw from the representation of a client if ... the representation will result in violation of the Rules of Professional Conduct or other law”). Even further, the attorneys had an affirmative duty to be truthful in their statements to others, including the DOJ and OIG during the course of the investigation. *See, e.g.*, S.C. Rules Prof. Cond. 4.1 (“In the course of representing a client a lawyer shall not knowingly: (a) make a false statement of material fact or law to a third person; or (b) fail to disclose a material fact when disclosure is necessary to avoid assisting a criminal or fraudulent act by a client . . .”); *see also* ABA Model Rule 4.1 (Truthfulness in Statements to Others). If the attorneys thought HDL was acting illegally, they would have had the ethical duty to withdraw and not perpetuate the fraud.

Further, as described above, Mallory disclosed the facts underlying the alleged false claims to the government. “The ‘government knowledge inference’ helps distinguish, in FCA cases, between the submission of a false claim and the *knowing* submission of a false claim – that is, between the presence and absence of scienter.” United States ex rel. Burlbaw v. Orenduff, 548 F.3d 931, 951 (10<sup>th</sup> Cir. 2008) (citations omitted). “A classic example is when the government, with knowledge of the facts underlying an allegedly false claims, authorizes the contractor to make that claim.” Id. at 952 (citing Wang v. FMC Corp., 975 F.2d 1412, 1421 (9<sup>th</sup> Cir. 1992) (“The government knew of all the deficiencies identified by Wang, and discussed them with FMC. The fact that the government knew of FMC’s mistakes and limitations, and that FMC was open with the government about them, suggests that while FMC might have been groping for solutions, it was not cheating the government in the effort”)); *see also* United States ex rel. Becker v. Westinghouse Savannah River Co., 305 F.3d 284, 288-89 (4<sup>th</sup> Cir. 2002); United States ex rel. Werner v. Fuentez System Concepts, Inc., 319 F. Supp. 2d 682 (N.D. W.Va. 2004).

There does not appear to be any administrative agency or court decision holding that the payment of P&H fees, payments pursuant to a contractor sales agreement, or the waiver of co-pays for Tricare is *per se* illegal. *See* Wilson, 525 F.3d at 376 (“imprecise statements or differences in interpretation growing out of a disputed legal question are [] not false under the FCA”). Mallory’s actions, positions, and interpretations were reasonable, and her actions were not designed to induce referrals. Because Mallory lacked even the lowest level of scienter, this Court should grant Mallory’s motion for summary judgment.

## **V. THE COURT SHOULD GRANT MALLORY SUMMARY JUDGMENT ON THE PLAINTIFF’S CONSPIRACY CLAIM**

The conspiracy claim is premised on the underlying FCA violations. (Complaint, ECF No. 75, ¶¶ 233-37). Because the government's individual claims fail, *see* Sections I-IV, *supra*, its conspiracy claim must also fail. United States ex rel. Godfrey v. KBR, Inc., 360 Fed. Appx. 407, 413 (4<sup>th</sup> Cir. 2010) (“Since Godfrey’s conspiracy claim is premised on those claims of underlying FCA violations, the conspiracy claim rises and falls with the individual claims”).

The conspiracy claim also fails because the plaintiff cannot demonstrate that (1) Mallory conspired with one or more persons to get a false or fraudulent claim allowed or paid by the United States, (2) one or more conspirators performed any act to effect the object of the conspiracy, (3) Mallory willfully joined that conspiracy, and (4) the United States has suffered damages as a result of the false or fraudulent claim. United States ex rel. Mikes v. Straus, 84 F. Supp. 2d 427, 432 (S.D.N.Y. 1999); United States ex rel. Miller v. Bill Harbert Intern. Const., Inc., 608 F.3d 871, 901 (D.D.C. 2010):

(1) There was no underlying violation of the FCA. Pencheng Si. V. Laogai Research Foundation, 71 F. Supp. 3d 73, 89 (D.D.C. 2014) (An “important civil conspiracy principle is that no conspiracy can exist without some underlying tortious act. In the context of the FCA, this means that there can be no liability for the conspiracy where there is no underlying violation of the FCA.” (citations and internal quotations omitted); *see also* Sections I-IV, *supra*; *see also* the BlueWave defendants’ Motion for Summary Judgment.

(2) There is no evidence that there was a conspiracy. *See, e.g., United States v. Toyobo Co. Ltd.*, 811 F. Supp. 2d 37, 50 (D.D.C. 2011) (“To state a claim under the FCA for conspiracy, a plaintiff must plead that the alleged conspirators agreed to make use of a false record or statement to achieve the end of getting the government to pay a claim”); United States ex rel. Reagan v. East Texas Medical Center Regional Healthcare System, 274 F.Supp.2d 824,

857 (S.D. Tex. 2003) (“the essence of a conspiracy under the FCA is an agreement between two or more persons to commit fraud. ... Courts agree that, to establish the existence of a civil conspiracy, a plaintiff must present evidence to show a meeting of the minds of two or more persons on the object or course of action. ... In the context of an FCA conspiracy, the evidence must show that the alleged conspirators shared a specific intent to defraud the government”). There is no such evidence here. As explained above, Mallory did not have a specific intent to defraud the government. There was no meeting of the minds. Rather, the BlueWave Sales Agreement was created and drafted by Attorney Ryan and analyzed by numerous other attorneys. *See* Sections I-IV, *supra*. Similarly, the P&H Agreement was drafted by Attorney Ryan and was analyzed by numerous other attorneys. *See* Sections I-IV, *supra*. Mallory continuously sought out and relied on the advice of counsel. She disclosed the facts underlying the alleged false claims to the government and the government continued to pay claims, even after it settled with HDL. *See Id.*

(3) There is no evidence that Mallory willfully joined a conspiracy. *See Miller*, 608 F.3d at 901; *see also* Section V(2), *supra*, and Sections I-IV, *supra*.

(4) The United States has not suffered damages as a result of the purported false or fraudulent claim. HDL’s tests were valuable and there is no evidence that the government did not receive the benefit of the tests.

## **VI. THE COURT SHOULD GRANT MALLORY’S SUMMARY JUDGMENT MOTION ON THE PLAINTIFF’S COMMON LAW CLAIMS**

“A claim for payment by mistake of fact allows the Government to ‘recover funds which its agents have wrongfully, erroneously, or illegally paid.’” *United States v. Fadul*, 2013 WL 781614, \*12 (D. Md. 2013) (quoting *United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742, 776 (N.D. Tex. 2003)). “Where it seeks to recover payments made as a result of false claims, the

Government must show that it ‘made payments under an erroneous belief which was material to the decision to pay.’” *Id.* (quoting United States v. Mead, 426 F.2d 118, 124 (9<sup>th</sup> Cir. 1970)); *see also* Medica-Rents Co., 825 F. Supp. 2d at 776 (the government must show “(1) payments were made (2) under the belief that they were properly owed; (3) that belief being erroneously formed; and (4) the mistaken belief was material to the decision to pay”). “[T]hree elements encompass the equitable remedy of unjust enrichment: the plaintiff must show that “(1) he had reasonable expectation of payment, (2) the defendant should reasonably have expected to pay, or (3) society’s reasonable expectations of a person and property would be defeated by nonpayment.” Provident Life & Acc. Ins. Co. v. Waller, 906 F.2d 985, 993-94 (4<sup>th</sup> Cir. 1990). “The doctrine of unjust enrichment applies to situations where there is no legal contract, but where the person sought to be charged is in possession of funds which in good conscience and justice should not be retained, but should be delivered to the rightful owner.” Medica-Rents Co., 285 F. Supp. 2d at 777 (citations omitted).

There is no evidence that “payments were made” to Mallory, that she “obtain[ed] government funds” to which she was not entitled, or that she is in possession of funds which in good conscience and justice should not be retained, but should be delivered to the rightful owner. *See* Complaint, ECF No. 75, ¶¶ 241, 244 Payments were made to HDL, but the government has put forth no evidence regarding what benefits Mallory “personally derived from the mistaken payments.” *See* United States v. Fadul, 2013 WL 781614, \*13 (D. Md. 2013).

When asked about what funds Mallory received with respect to the unjust enrichment claim, the government stated that Mallory personally obtained money “in the form of salary, bonuses, travel and other reimbursement and shareholder disbursements, from HDL, which funds were the direct and indirect result of the illegal conduct alleged in the Complaint in Intervention,

and consisted of Medicare and TRICARE payments HDL caused by the false claims alleged in the Complaint in Intervention ...” ECF No. 397-15 (Plaintiff’s Responses to Interrogatories No. 16). However, it is not enough to assume that Mallory received a personal benefit because she was the CEO of HDL. *See Id.* (In fact, it is not even “enough to assume that [the defendant] received a personal benefit because he is the only member and officer of CVC”). HDL was a corporation with a Board of Directors, numerous officers, and 1,000 employees. The government paid claims through August 2015, almost a year after Mallory left HDL, 6 months after the government entered into a settlement agreement with HDL, and a month after HDL filed bankruptcy.

Further, the alleged wrongfully paid reimbursements may have been used for other purposes, *e.g.*, HDL paying the government pursuant to its settlement agreement, paying attorneys millions of dollars, paying the salaries and bonuses of other HDL employees and officers, for getting Project Twilight implemented, and for numerous other operating expenses. *See Fadul*, 2013 WL 78614, \*7 (“The wrongfully paid reimbursements may have been used for other purposes (*e.g.*, paying the salaries and omissions of CVC employees; compensating the third-party technicians and radiologists; and any number of operating expenses”). There is nothing to justify piercing the corporate veil based on the theory that HDL functioned merely as Mallory’s alter ego. *See Id.*

Moreover, the government did not “erroneously” form any belief that was “material” to its decision to pay. It fully knew of the underlying conduct and continued to pay claims. “Under any understanding of the concept, materiality ‘look[s] to the effect on the likely or *actual behavior* of the recipient of the alleged misrepresentation.’” Universal Health Services, Inc., 136 S.Ct. at 2002 (quoting 26 R. Lord, *Williston on Contracts* § 69:12, p. 549 (4<sup>th</sup> ed. 2003)) (italics

added). As demonstrated above, the alleged misrepresentations were not material and the government did not “erroneously” pay claims. The government’s common law claims fail.

## **VII. INCORPORATION OF THE BLUEWAVE DEFENDANTS’ ARGUMENTS**

Mallory hereby incorporates the arguments as set forth by BlueWave Healthcare Consultants, Inc., Floyd Calhoun Dent, III, and Robert Bradford Johnson by reference, as if fully stated herein.

## **CONCLUSION**

For the reasons demonstrated herein, the Court should grant Mallory’s motion for summary judgment.

This 23<sup>rd</sup> day of June, 2017

Respectfully submitted,

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